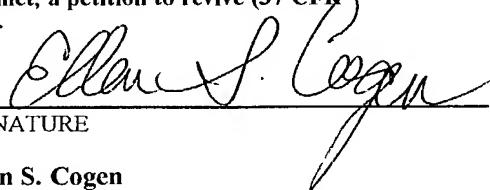


FORM PTO-1390 (Modified) (REV 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER TO THE UNITED STATES		DESIGNATED/ELECTED OFFICE (DO/EO/US)		U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)
CONCERNING A FILING UNDER 35 U.S.C. 371				10/019873
INTERNATIONAL APPLICATION NO PCT/US00/08695	INTERNATIONAL FILING DATE 30 March 2000			PRIORITY DATE CLAIMED 30 March 1999
TITLE OF INVENTION <b>METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION</b>				
APPLICANT(S) FOR DO/EO/US <b>IDEKER, Raymond E. and GIROUARD, Steven D.</b>				
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:				
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)) The submission must include items (5), (6), (9) and (24) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau)</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4)</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3))</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))</li> <li>11. <input checked="" type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</li> <li>12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</li> </ol>				
Items 13 to 20 below concern document(s) or information included:				
<ol style="list-style-type: none"> <li>13. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>15. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>17. <input type="checkbox"/> A substitute specification.</li> <li>18. <input type="checkbox"/> A change of power of attorney and/or address letter</li> <li>19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1821 - 1825</li> <li>20. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4)</li> <li>21. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>22. <input checked="" type="checkbox"/> Certificate of Mailing by Express Mail</li> <li>23. <input checked="" type="checkbox"/> Other items or information postcard</li> </ol>				
 <b>25006</b> <small>PATENT TRADEMARK OFFICE</small>				

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5) <b>10/019873</b>	INTERNATIONAL APPLICATION NO. <b>PCT/US00/08695</b>	ATTORNEY'S DOCKET NUMBER <b>UAB-15602/22</b>																
24. The following fees are submitted:		<b>CALCULATIONS PTO USE ONLY</b>																
<b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :</b>																		
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . . . . . <b>\$1040.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . . <b>\$890.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . . <b>\$740.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . <b>\$710.00</b> <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . . <b>\$100.00</b>																		
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Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)).		<input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 <b>\$130.00</b>																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">CLAIMS</th> <th style="width: 25%;">NUMBER FILED</th> <th style="width: 25%;">NUMBER EXTRA</th> <th style="width: 25%;">RATE</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>44 - 20 =</td> <td>24</td> <td>x \$18.00    <b>\$432.00</b></td> </tr> <tr> <td>Independent claims</td> <td>4 - 3 =</td> <td>1</td> <td>x \$84.00    <b>\$84.00</b></td> </tr> <tr> <td colspan="2">Multiple Dependent Claims (check if applicable).</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><b>\$0.00</b></td> </tr> </tbody> </table>		CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	44 - 20 =	24	x \$18.00 <b>\$432.00</b>	Independent claims	4 - 3 =	1	x \$84.00 <b>\$84.00</b>	Multiple Dependent Claims (check if applicable).		<input type="checkbox"/>	<b>\$0.00</b>	
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<input checked="" type="checkbox"/> Applicant claims small entity status See 37 CFR 1.27). The fees indicated above are reduced by 1/2		<b>\$373.00</b>																
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a. <input checked="" type="checkbox"/> A check in the amount of <b>\$373.00</b> to cover the above fees is enclosed b. <input type="checkbox"/> Please charge my Deposit Account No _____ in the amount of _____ to cover the above fees A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No <b>07-1180</b> A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card <b>WARNING: Information on this form may become public. Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.																		
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>																		
SEND ALL CORRESPONDENCE TO. <div style="border: 1px solid black; padding: 5px; display: inline-block;">           Ellen S. Cogen            Gifford, Krass, Groh, Sprinkle,            Anderson &amp; Cikowski, P.C.            280 N. Old Woodward Avenue, Suite 400            Birmingham, MI 48009-5394            (248) 647-6000         </div>																		
 SIGNATURE Ellen S. Cogen NAME 38,109 REGISTRATION NUMBER 10/25/01 DATE																		

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10 Reg. PCT 973 26 OCT 2001

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## METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

### Technical Field

The subject invention relates to a method and apparatus for cardiac stimulation. In particular, the subject invention provides a passive conductor for use in combination with an implanted stimulating device for passively stimulating remote regions of the heart and a method of using same.

### Background of the Invention

By way of background, the application of electrical current to the heart through electrodes either applied directly to the chest or through an implanted device is well known in the art. Typical implanted devices include defibrillators and/or pacemakers. These types of devices are usually surgically implanted into a subject and an intracavitory electrode is placed within or adjacent to the heart, typically transvenously.

While these implanted stimulating devices competently carry out their design task, there are many instances in which it would be desirable to electrically stimulate a portion of the heart that is either difficult to reach with a transvenously disposed electrode or which has been previously connected to an implanted electrode. For example, locations such as, but not limited to, the left ventricular apex, the anterior-basal left ventricular free wall, and the left atrium near the pulmonary veins. It may be necessary and advantageous to electrically stimulate the heart from these regions for reasons including multi-site pacing for congestive heart failure, single or multi-site pacing to prevent a ventricular or atrial tachyarrhythmia, single or multi-site pacing very soon after the onset of

an arrhythmia to halt the arrhythmia before it degenerates into ventricular or atrial fibrillation requiring a defibrillation shock, and multi-site electrodes for delivery of shocks with a lower defibrillation threshold than shocks delivered only through transvenous electrodes.

5 While electrodes on catheters inserted into veins of the heart by way of the coronary sinus can be placed in many cardiac locations, there are a number of spots or locations to which they cannot reach or be placed. Electrodes can be placed in almost any desired epicardial location during open-heart surgery. However, such surgery is expensive and is associated with both mortality and 10 morbidity of the subject. With the advent of thoracoscopic surgery, it is now possible to implant such electrodes in the pericardial space by a much more minor procedure that requires only one or two small incisions for the insertion of a thoracoscopic device. However, this type of procedure is still complicated by the fact that the electrodes still must be connected to wires that are tunneled 15 through the body to the pacemaker or defibrillator.

It has been recognized that the heart is under profound control of the autonomic nervous system. There are many instances when electrical stimulation of the neural input to the heart could be beneficial for the alteration 20 of cardiac electrophysiologic status. The difficulty in implementing neural stimulation of the heart has been in the development of an apparatus for the direct stimulation or inhibition of cardiac sympathetic and parasympathetic nerves.

Accordingly, it would be advantageous and desirable to have an apparatus and method for stimulating portions of the heart which are difficult or impossible to reach or stimulate with a transvenous electrode but which are accessible utilizing the less invasive thoracoscopic surgical technique and which is able to stimulate the remote regions of the heart without the necessity for tunneling wires through a body of the subject and connection to a pacemaker or defibrillator for a source of electrical stimuli.

Furthermore, it would also be advantageous and desirable to have a method and apparatus which allows for the selective stimulation of the heart.

10

#### Summary of the Invention

A passive conductor assembly for use with an implanted stimulating device having an intracavarily or transvenously disposed electrode is disclosed. The passive conductor assembly for use in combination with the implanted stimulus generator having an intracavarily or intravenously disposed electrode includes at least one conductive element having a first end and a second end, and/or other contact sites for contacting a desired or selected portion of a heart of a subject to be stimulated. The passive conductor assembly is disposed in proximity to the intracavarily or transvenous electrode which is connected to the implanted stimulus generator such as a pacemaker or defibrillator. Upon discharge of an electrical stimulus or waveform from the implanted stimulus generator, the stimulus is conducted through the myocardial tissue to the conductor where it is passively conducted to a region of the heart in contact with an end or other contact sites of the

conductive element of the passive conductor assembly which have been selected for cardiac stimulation.

The passive conductor assembly can include electrical components disposed in electrical communication therewith to provide for the manipulation and/or modification of the electrical stimulus or waveform generated by the implanted stimulus generator which can be designed, for example, to selectively stimulate only neural tissue and not cardiac tissue or vice versa through the same passive conductor assembly.

**Brief Description of the Drawings**

10 The following detailed description is best understood with reference to the following drawings in which:

Figure 1 illustrates the potential field from a 500-V 6ms unsuccessful defibrillation shock. The top two panels represent the subepicardial potentials, and the bottom two panels represent the subendocardial potentials. All panels show the potentials superimposed on the epicardial surface of the heart. The two panels on the left represent the left antero-lateral view of the heart, whereas the two panels on the right represent the right postero-lateral view of the heart. Numbers denote the location of the recording electrodes and the potential in volts recorded at each site. Isopotential lines are separated by 25V.

15 Solid circles represent locations where good recordings were not obtained. The dashed line indicates the upper border of the right ventricular outflow tract.

20 *LV* = left ventricle; *RV* = right ventricle; *RVOT* = right ventricular outflow

tract; *LAD* = left anterior descending coronary artery; *RCA* = right coronary artery; *Cx* = circumflex coronary artery.

#### Detailed Description of the Invention

The present invention provides for a passive conductor assembly used in combination with an implanted cardiac stimulation device or generator such as a pacemaker or a defibrillator having an intracavitarily or intravenously disposed electrode. The passive conductor assembly can be placed by surgery or thoracoscopy to electrically stimulate the heart of a subject which does not require the running or tunneling of wires from the passive conductor assembly to the implanted stimulus generator. That is, the passive conductor assembly can be completely self-contained or disposed completely within the pericardial space of the heart and used in conjunction with a defibrillator or a pacemaker connected to leads or electrodes that are inserted into the heart.

The passive conductor assembly includes at least one conductive element having a first end, a second end, and/or other contact sites for contacting a portion of the heart of the subject. The conductive element is preferably comprised of a low-resistance material and can have any suitable length but typically ranges from approximately 1 cm to approximately 12 cm. The conductive element can be made of any conductive material but is preferably constructed of a metallic material in the form of wire or strips that are placed in the pericardial space and contact the heart. Additionally, the conductive element can be constructed of a composite ribbon of conductive material. The conductive elements can be exposed to the heart along their

entire length forming a single electrode, however, in a preferred embodiment, the conductive element is insulated along most of its length except at the two ends or other intermediate sites which form the electrodes or contact sites.

5 The insulator can comprise any suitable electrically insulative material that is also biocompatible. In a further embodiment, the insulation can be removed at one or more additional locations along the conductive elements to stimulate additional sites of the heart.

10 The ends of the conductive element should be placed at the points on the heart at which the electrical stimulus or waveform delivered by the pacemaker or the defibrillator, through their own transvenous electrode, creates a potential differential on the surface of the heart to facilitate the flow of the electrical stimulus. That is, if the two ends of the conductive element are placed at sites that have approximately the same electrical potential, little or no 20 current will flow therethrough.

15 The exposed portions (ends and/or regions therebetween) of the conductive element in the contact with the heart can vary in size depending on the current density and the potential gradient in the immediately adjacent tissue. Typically, the contact portion of the conductive element can range from approximately 0.2 mm to 4 cm.

20 In order to modify the electrical stimulus or waveform received from the implanted stimulus generator, electrical components can be disposed in electrical communication with or along the conductive element. These electrical components can include, for example, diodes, devices capable of

storing energy such as capacitors, microprocessors, resistors, and the like. The electrical components can also be used in combinations such that the passive conductor can act as a low-pass or high-pass filter to modify the input stimulus or waveform from the implanted stimulus generator. In another embodiment, a 5 diode could be placed along the conductive element such that the stimulus or electrical current could only flow in one direction along the conductive element during the stimulation. This embodiment has several advantages, for example, it becomes possible to pace from some sites in the heart but not others by controlling which polarity of stimulus was generated by the implanted stimulus 10 generator through its electrode(s). If two or more conductors are utilized, then the diode could be oriented in one direction for some of the electrodes and oriented in the opposite direction for other of the electrodes so that the first set of electrodes would pass current with one polarity while the other set would pass current of the other polarity. An additional set of conductors could 15 contain no diode such that they would pass current with either polarity. The use of electrical components disposed along the conductive element increases the flexibility of stimulating of myocardium in different combinations and in different sequences.

Diodes may also be useful for delivering defibrillation and 20 cardioversion shocks. A concern when delivering a shock through two or more electrodes that are of the same polarity and the same or nearly same strength, is that a region of little current flow and potential gradient will be created on the heart at the point somewhere between the common polarity electrodes.

Creation of this low field region could significantly increase the defibrillation and cardioversion thresholds. Currently, most defibrillation shocks are biphasic with a second phase opposite in polarity to the first phase. The presence of the diode in one or more of the conductive elements would allow current to flow during one phase but not the other phase of the biphasic waveform. Therefore, the region of low field strength would only be present during one of the two phases of the shock so that the area could receive a stronger defibrillating field strength during the other phase.

In a further embodiment designed to avoid the region of low field strength throughout all phases of the shock, a capacitor is utilized instead of a diode along the length of the conductive element. The capacitor would allow current to flow during the early portion of the shock pulse thereby creating the low field strength region, but would not allow much current to flow later during the pulse, at which time the low field strength region would no longer be of the same strength and location. Towards the end of the shock pulse and after the shock pulse, the capacitor would discharge, creating a biphasic shock effect in some portions of the heart. If the shock pulse delivered from the defibrillator is, itself, biphasic, the second phase could be delivered either immediately after the first phase or after an interval of up to 5 ms or more since it has been shown that such a separation does not significantly decrease the beneficial effects of a biphasic pulse on defibrillation. Cooper et al. *Pace*, 16:471-482 (1993). Thus, with a short interval between the two phases of the shock, the capacitor would discharge during the second phase either partially or

entirely followed by charging in the opposite polarity toward the end of the second phase. This interaction would change the ratio of the currents passing through the passive conductor assembly and through the active intravascular defibrillation electrodes throughout the pulses. Accordingly, the size and 5 location of the low field regions should change throughout the pulses instead being fixed in one region. The movement of this low field strength region should have a beneficial effect on the defibrillation threshold.

Alternatively, the two active phases of the shock could be separated by up to 5 or more ms so that the capacitor will largely discharge between the two 10 phases and following the second active phase.

Biphasic pulses are frequently used for pacing to prevent electrolysis and the plating or the unplating of the pacing electrodes that can occur with a single polarity pulse. Disposing a capacitor along the length of the conductor would generate a biphasic pacing pulse since it allows only a zero net charge to 15 pass through the conductor after it has been discharged.

Other electronic components used in combination with the passive conductor assembly could be useful. These components could be powered by the current that passes through the conductive element when a stimulus is delivered through the active intravascular electrodes of the pacemaker or defibrillator. Electronic components could store the charge to power the other 20 components disposed along the conductive element for some period of time following pulses delivered by the pacemaker or the defibrillator. The pulses to charge these electronic components could either be delivered whenever needed

to treat or prevent arrhythmias or the pacemaker or defibrillator could deliver a small stimulus at specific time intervals for the sole purpose of charging the components disposed along the conductive element. This small stimulus could be of a frequency that does not stimulate the myocardium.

5        The electronic components that are powered along the conductive elements could perform several functions, for example, sensing activations at the ends or contacts on the conductive element. Pacing stimuli or shocks at these points along the conductive element could be time-based on the recorded activations from these electrodes. The timing algorithms could be performed  
10      by the electronic components disposed along the conductive element. Alternatively, the power in the conductive element could be used to pass a signal to the pacemaker or the defibrillator or its recording electrodes so that the software within the pacemaker or the defibrillator could control and integrate the responses of all of the passive conductors. Communication  
15      signals between the components disposed along the conductive element of the passive conductor and the pacemaker or the defibrillator could be by any modality including electrical or optical. If electrical, the frequency and strength of the signal could be such that the signal does not cause stimulation of the heart.

20      The passive conductor assembly is preferably oriented so that, during an electrical pulse delivered by the separated implanted stimulus generator, a potential difference is generated between the ends or other exposed regions (electrodes) of the conductive element disposed in the pericardial space.

Typically, at least one of the electrodes will be placed on the epicardium overlying one of the implanted stimulus generator leads or electrodes located within the cavities of the heart or veins. However, other orientations may also be useful. For example, as reported in a study by Callahan et al., (JACC, 1995; 5 25:1373-1379), it was found that a passive patch electrode located distant from the defibrillation electrodes of an implanted cardioverter/defibrillator would transfer most of the potential gradient that would normally be present beneath this electrode to concentrate it at the edges of the electrode. For a small 10 electrical stimulus, this effect may make it possible to pace from the edge of the electrode with an electrical stimulus that would not be strong enough to pace this region in the absence of the passive conductor.

As stated above, the present invention provides a method and device for the stimulation or the inhibition of neural inputs to the heart with the purpose of preventing atrial or ventricular arrhythmias, terminating atrial or ventricular 15 arrhythmias, assisting in atrial or ventricular defibrillation, control of heart-rate variability, or the improvement of cardiac function. By adding the passive electrical components to the passive conductive element and modulating the frequency of stimulation of the intracavitory electrode therewith, the present invention allows for selective stimulation and/or inhibition of neural tissue and 20 not cardiac tissue or vice versa through the same passive conductor assembly.

The device for the extra-cardiac stimulation or inhibition of neural inputs to the heart is similar if not identical to the device described immediately above. The uninsulated portions (electrodes) of at least one conductive

element are disposed in contact with the heart and/or other tissues such as neural tissue, fat pads containing post-ganglionic neural fibers, cardiac veins adjacent to neural fibers, or other electrically excitable tissues such as the stellate ganglia and the vagus. The conductive element can also run circumferentially along the atrial-ventricular groove of the heart such that the sympathetic and the parasympathetic innervation, running parallel to cardiac vasculature, can be directly stimulated or inhibited. Typically, the electrical stimulation or inhibition will be achieved with the application of stimuli from approximately 1 to 20 mA at a frequency of approximately 1 to 50Hz. For neural stimulation, the stimulus could have a pulse width from approximately 10-250  $\mu$ sec, a current of approximately 1-20 mA, and a frequency of approximately 1-50Hz. For cardiac stimulation, the stimulus could have a pulse width from approximately 0.5-2 msec, a current of approximately 1-20 mA and a frequency of approximately 1-5Hz.

The conductive element should be oriented such that when an electrical stimulus or pulse is delivered from the implanted stimulus generator, an electrical potential difference will be created on the epicardial surface between the two or more exposed electrodes on the conductive element. As a result of this potential difference, current will be induced to flow in the conductive element. To achieve a sufficient potential difference in the passive conductor assembly, at least one conductive element should be placed in close proximity to the cardiac tissue overlying either an intracavitory electrode in an atrial or ventricular chamber, cardiac vein, or other location in or near the heart.

Alternatively, the passive conductor assembly having at least one conductive element may be placed in the pericardial space, an extra-pericardial space, or in other extra-cardiac locations. The passive conductor assembly can be placed during surgery that exposes these locations directly or may be placed 5 using minimally invasive techniques such as thoracoscopic surgery, or transvenously through an introducing catheter. Additionally, passive conductor assemblies for both neural stimulation/inhibition can be combined with passive conductor assemblies for directly exciting cardiac tissue.

The largest effect utilizing the passive conductor assembly of the 10 present invention is generally seen when one end of the conductive element is placed directly on the epicardium over the intravenous electrode of the stimulus generating device. However, this does not have to be the case. In order to refine the placement of the passive conductor assembly, it may be helpful to map the regions of the heart that depolarize and hyperpolarize in the absence of 15 the passive conductor assembly during a stimulus passed through the intravenous electrode. The implanted stimulus generator should cause hyperpolarization at one end and depolarization at the other. Accordingly, it should be possible to place the passive conductor assembly in a region that is normally undergoing depolarization induced by the stimulus. These two 20 effects should be additive so that the amount of stimulus needed to directly stimulate the particular region or area of the heart should be lower than when the end of the conductive element that causes depolarization is placed in a region that is undergoing hyperpolarization caused by the electrical stimulus

through the transvenously disposed electrodes. It is also possible that a similar beneficial effect might be seen if the end of the conductive element that causes hyperpolarization is placed in a region that is already undergoing hyperpolarization during the electrical stimulus.

5 As is stated above, more than one passive conductor assembly can be used in the same subject. For example, arrhythmias may be prevented by simultaneously stimulating from several sites on the heart. Two, three, or even more of the passive conductor assemblies could be placed in the pericardial space to pace from all of the sites. Even though the stimulus strength will be  
10 larger than if it was directly paced at each of the sites with electrodes connected directly to the implanted stimulus generator, the strength of the electrical stimulus should still be smaller than that required to directly activate all of these regions by a stimulus from the transvenous electrodes in the absence of the passive conductors of the present invention.

15 The passive conductor assembly of the present invention can be used for prevention and treatment of atrial-arrhythmias, ventricular arrhythmias, as well as for the control of cardiac performance through control of heart rate and atrial and ventricular refractory periods. Additionally, the passive conductor assembly can be used for the control of heart rate through stimulation of neural  
20 inputs to the sino-atrial and atrial-ventricular nodes of the heart.

Use of the passive conductor assembly of the present invention may be useful for augmenting traditional therapies such as antitachycardia pacing by altering the excitable gap through neural stimulation, thus improving the

probability of pace termination of arrhythmias. Analogously, the passive conductor assembly and method for use thereof for neural stimulation may be beneficial for lowering the energy requirements for electrical termination of atrial or ventricular fibrillation. Neural stimulation can slow or even halt impulse propagation from the atria to the ventricles. Thus, the passive conductor assembly of the present invention should allow for control of the ventricular response to premature atrial contractions by slowing or stopping impulse propagation at the atrial-ventricular node. By causing transient heart block through neural stimulation, supra-ventricular arrhythmias such as Wolf-Parkinson-White Syndrome, atrial-ventricular nodal re-entrant tachycardia, atrial fibrillation or atrial flutter with rapid ventricular response and other arrhythmias may be successfully prevented, terminated, or controlled.

The utility of the compositions and methods according to the present invention are shown below in the Example section.

#### 15 EXAMPLES

An example of the possible use of the passive conductor of the present invention is illustrated in Figure 1. Figure 1 illustrates the distribution of potentials generated with electrodes in the right ventricular cavity and on the skin of the left lower thorax. Even though the potential did change rapidly with distance in the lateral-apical left ventricle in the region marked A, signifying the potential gradient as low, the potential in this region for a 500V defibrillation shock was 83V more than the value on the epicardium overlying the electrode in the right ventricle in the region marked B [-48V-)-131V)]. If a

wire was attached to the epicardium at these spots, current should flow through the wire and the potential gradient should be increased in the lateral-apical left ventricle. This should allow stimulation of the tissue in the lateral-apical left ventricle region with a much weaker stimulus than required in the absence of the wire.

For example, in the preferred embodiment of the invention an electric wire 100 has one end 102 both electrically and mechanically attached to a preselected region 104 of the heart, e.g. by suturing. A second end 106 of the wire 100 is both electrically and mechanically connected to a different region 108 of the heart, also preferably by suturing. Since the heart regions 104 and 108 of the heart attain different electric potentials during cardiac contraction, current flows through the wire thus achieving passive stimulation of the myocardium.

The wire 100 is electrically insulated in any conventional fashion between its ends 102 and 106. However, one or more points of the wire 100 between its ends may be electrically connected to the heart to provide passive stimulation during cardiac contraction.

As another example, the area near the pulmonary veins appears to frequently play a role in the induction and/or maintenance of atrial fibrillation. This is also the region in which the effect of the shock is weakest for electrodes in the right atrium and the distal coronary sinus as shown by Cooper et al. (Herzschr Elektrophys, 1998; 9:1-7). It should be possible to run a conductor to this region by way of the transverse sinus in the pericardial space. Such an

electrode location should be beneficial for pacing to prevent atrial fibrillation, for giving a small pacing or shocking stimulus or stimuli just as atrial fibrillation begins, or for giving a defibrillation shock to halt atrial fibrillation once it is established.

5 Other descriptive and exemplary materials are provided in Appendix A herewith.

In view of the teaching presented herein, other modifications and variations of the present inventions will be readily apparent to those of skill in the art. The foregoing drawings, discussion, and description are illustrative of 10 some embodiments of the present invention, but are not meant to be limitations on the practice thereof. It is the following claims, including all equivalents, which define the scope of the invention.

Any patents or publications mentioned in this specification are 15 indicative of the levels of those skilled in the art to which the invention pertains. These patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

Claims

What is claimed:

1        1. A method of electrically stimulating selected regions of a  
2        subject's heart having an implanted stimulus generator having an intracavitarily  
3        disposed electrode disposed in the subject, said method comprising the steps  
4        of:

5                inserting into the subject at least one conductor having at least two  
6        electrical contacts thereon;

7                contacting a portion of the heart to be stimulated with the electrical  
8        contact of the conductor;

9                positioning the electrical contact of the conductor in contact with  
10        myocardial tissue such that an electrical stimulus delivered by the implanted  
11        stimulus generator creates an electrical potential difference at each contact of  
12        the conductor;

13                generating a stimulus from the implanted stimulus generator; and

14                discharging the electrical stimulus from the intracavitarily disposed  
15        electrode wherein the stimulus is conducted through the myocardial tissue and  
16        through at least one electrical conductor and is transferred to the regions of the  
17        heart contacting the electrical contacts of the conductor, whereby the current is  
18        sufficient to stimulate tissue of the heart.

1        2. A method according to claim 1, wherein said inserting step  
2        further comprises surgically implanting the conductor.

1           3.    A method according to claim 2, wherein said surgically  
2    implanting step is further defined as thoroscopically implanting the conductor.

1           4.    A method according to claim 1, wherein the implanted stimulus  
2    generator is selected from the group consisting of a pacemaker and a  
3    defibrillator.

1           5.    A method according to claim 1, wherein the conductor  
2    comprises an insulator disposed about at least a portion of the conductor.

1           6.    A method according to claim 1, wherein the conductor  
2    comprises a metallic wire.

1           7.    A method according to claim 1, wherein the conductor  
2    comprises a metallic strip.

1           8.    A method according to claim 1, wherein the conductor  
2    comprises a ribbon of conductive material.

1           9.    A method according to claim 1, wherein the conductor includes  
2    at least one electrical component disposed in electrical communication  
3    therewith.

1           10.    A method according to claim 9, wherein the electrical  
2           component comprises a diode.

1           11.    A method according to claim 9, wherein the electrical  
2           component comprises a device capable of storing energy.

1           12.    A method according to claim 11, wherein the electrical  
2           component comprises a capacitor.

1           13.    A method according to claim 9, wherein the electrical device  
2           comprises a resistor.

1           14.    A method according to claim 9, wherein the electrical  
2           component comprises a microprocessor.

1           15.    A passive conductor assembly for use with an implanted  
2           stimulus generator having an intracavitarily disposed stimulating lead for  
3           stimulating the heart of a subject, said conductor assembly comprising:  
4           at least one conductive element having at least two electrically  
5           conductive contacts for contacting a portion of the heart of the subject.

1           16. A conductor as set forth in claim 15, wherein said conductive  
2           element comprises an insulator disposed about at least a portion of said  
3           conductive element.

1           17. A conductor as set forth in claim 15, wherein said conductive  
2           element comprises a metallic wire.

1           18. A conductor as set forth in claim 15, wherein said conductive  
2           element comprises a metallic strip.

1           19. A conductor as set forth in claim 15, wherein said conductive  
2           element comprises a ribbon of conductive material.

1           20. A conductor as set forth in claim 15, wherein said conductive  
2           element includes at least one electrical component disposed in electrical  
3           communication therewith.

1           21. A conductor as set forth in claim 20, wherein said electrical  
2           component comprises a diode.

1           22. A conductor as set forth in claim 20, wherein said electrical  
2           component comprises a device capable of storing energy.

1           23. A conductor as set forth in claim 22, wherein said electrical  
2           component comprises a capacitor.

1           24. A conductor as set forth in claim 20, wherein said electrical  
2           component comprises a resistor.

1           25. A conductor as set forth in claim 20, wherein said electrical  
2           component comprises a microprocessor.

1           26. A method of neurally stimulating the heart of a subject, said  
2           method comprising the steps of:  
3                 disposing at least one conductor having at least two electrically  
4                 conductive contacts adjacent to a portion of a heart in close proximity to an  
5                 intracavitarily disposed electrode of an implanted stimulus generator;  
6                 contacting a portion of the heart with the electrically conductive  
7                 contacts of the conductor;  
8                 positioning the electrically conductive contacts of the conductor in  
9                 contact with myocardial tissue such that an electrical stimulus delivered by the  
10                 implanted stimulus generator creates an electrical potential difference at each  
11                 of the electrically conductive contacts of the conductor inducing the flow of  
12                 current therethrough; and  
13                 generating an electrical stimulus from the implanted stimulus generator  
14                 and discharging the electrical stimulus from the intracavitarily disposed

15       electrode wherein the stimulus is conducted through the myocardial tissue and  
16       through at least one electrically conductive contact and is conducted to the  
17       regions of the heart contacting other of the electrically conductive contacts of  
18       the conductor; and  
19                   selectively stimulating neural tissue of the heart.

1               27.    A method according to claim 26, wherein said inserting step  
2       further comprises surgically implanting the conductor.

1               28.    A method according to claim 27, wherein said surgically  
2       implanting step is further defined as thoroscopically implanting the conductor.

1               29.    A method according to claim 26, wherein the implantable  
2       stimulus generator is selected from the group consisting of a pacemaker and a  
3       defibrillator.

1               30.    A method according to claim 26, wherein the conductor  
2       comprises an insulator disposed about at least a portion of the conductor.

1               31.    A method according to claim 26, wherein the conductor  
2       comprises a metallic wire.

1           32. A method according to claim 26, wherein the conductor  
2           comprises a metallic strip.

1           33. A method according to claim 26, wherein the conductor  
2           comprises a ribbon of conductive material.

1           34. A method according to claim 26, wherein the conductor  
2           includes at least one electrical component disposed in electrical communication  
3           therewith.

1           35. A method according to claim 34, wherein the electrical  
2           component comprises a diode.

1           36. A method according to claim 26, wherein the electrical  
2           component comprises a microprocessor.

1           37. A method according to claim 34, wherein the electrical  
2           component comprises a device capable of storing energy.

1           38. A method according to claim 37, wherein the electrical  
2           component comprises a capacitor.

1           39.    A method according to claim 34, wherein the electrical device  
2    comprises a resistor.

1           40.    A method according to claim 26, wherein said selectively  
2    stimulating step further includes modifying the electrical stimulus prior to  
3    contacting the heart whereby the stimulus substantially only stimulates neural  
4    tissue.

1           41.    A method for electrically stimulating a preselected area of a  
2    heart comprising the steps of:

3               attaching one end of an electric wire to a first area of the heart so that  
4    said one end of said wire is in electrical contact with said first area of the heart,  
5    and

6               attaching a second end of an electric wire to the preselected area of the  
7    heart so that said second end of said wire is in electrical contact with said first  
8    preselected area of the heart,

9               wherein said first and said preselected areas of the heart attain different  
10   electrical potential levels during cardiac contraction.

1           42.    The invention as defined in claim 41 wherein said wire includes  
2    electrical insulation between its ends.

1           43. The invention as defined in claim 41 wherein each attaching  
2       step comprises the step of suturing said wire to the heart.

1           44. The invention as defined in claim 41 and comprising the step of  
2       attaching at least one intermediate point of said wire to the heart so that said  
3       intermediate point of the wire is in electrical contact with the heart.

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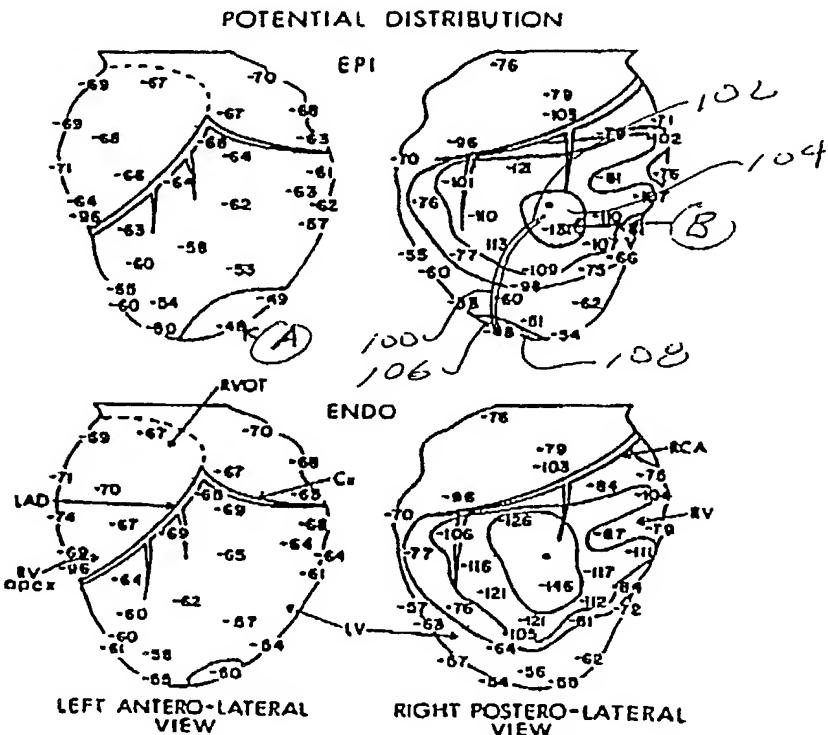
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(71) Applicant (for all designated States except US): UAB RESEARCH FOUNDATION [US/US]; AB1120G, 1530 3rd Avenue South, Birmingham, AL 35294-0111 (US).		
(72) Inventors; and		
(75) Inventors/Applicants (for US only): IDEKER, Raymond, E. [US/US]; 2600 Arlington Avenue South, Unit 76, Birmingham, AL 35205 (US). GIROUARD, Steven, D. [US/US]; 8155 Boulder Ridge Road, Woodbury, MN 55125 (US).		
(74) Agents: COGEN, Ellen, S. et al.; Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C., Suite 400, 280 N. Old Woodward Avenue, Birmingham, MI 48009 (US).		

(54) Title: METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

(57) Abstract

This invention is a passive conductor assembly for use with an implanted device having an intra-cavicularly or trans-venously disposed electrode. The assembly can include electrical components in electrical communication therewith which provide for the manipulation, and/or modification of the electrical stimulus or waveform generated by the implanted stimulus generator, which can be designed, for example, to selectively stimulate only neural tissue, not cardiac tissue or vice versa through the same passive conductor assembly.



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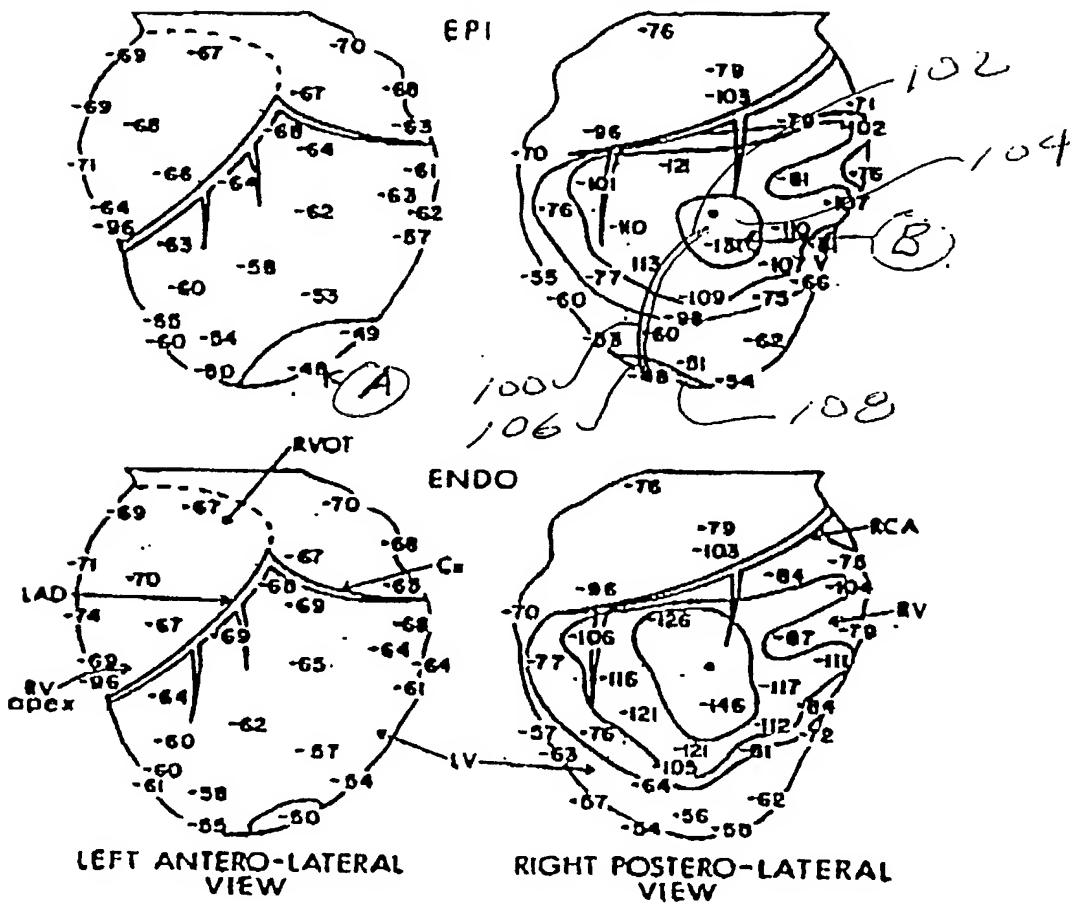


FIGURE 1

Docket No.  
UAB-15602/22

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As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

#### METHOD AND APPARATUS FOR PASSIVE CARDIAC STIMULATION

the specification of which

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I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

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60/126,867

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(Filing Date)

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(Status)

(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)

(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)

(patented, pending, abandoned)

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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

Ernest I. Gifford, 20,644  
 Allen M. Krass, 18,277  
 Irvin L. Groh, 17,505  
 Douglas W. Sprinkle, 27,394  
 Thomas E. Anderson, 31,318  
 Ronald W. Citkowski, 31,005  
 Judith M. Riley, 31, 561  
 Douglas J. McEvoy, 34,385

Ellen S. Cogen, 38,109  
 John G. Posa, 37,424  
 Roberta J. Morris, 33,196  
 Avery N. Goldstein, 39,204  
 Douglas L. Wathen, 41,369  
 Mark D. Schneider, 43,906  
 Beverly M. Bunting, 36,072

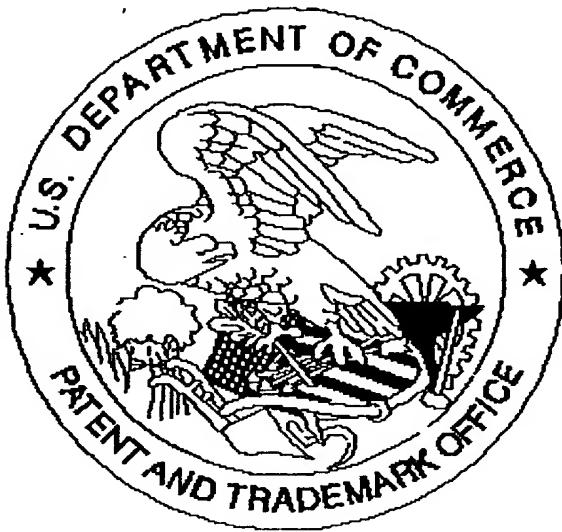
Send Correspondence to: Ellen S. Cogen  
Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C.  
280 N. Old Woodward Avenue, Suite 400  
Birmingham, MI 48009-5394

Direct Telephone Calls to: (name and telephone number)  
 Ellen Cogen at (248) 647-6000

Full name of sole or first inventor <u>Raymond E. Ideker</u>	Date <u>4/4/02</u>
Sole or first inventor's signature <u>Raymond E. Ideker</u>	
Residence <u>Birmingham, Alabama</u> <u>AL</u>	
Citizenship <u>US</u>	
Post Office Address <u>2600 Arlington Ave. South, # 76</u>	
<u>Birmingham, AL 35205</u>	

Full name of second inventor, if any <u>Steven D. Girouard</u>	Date <u>4.23.2002</u>
Second inventor's signature <u>SDG</u>	
Residence <u>Woodbury, Minnesota</u> <u>MN</u>	
Citizenship <u>US</u>	
Post Office Address <u>8155 Boulder Ridge Rd.</u>	
<u>Woodbury, MN 55125</u>	

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